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Test-retest reliability, concurrent validity and correlates of the two-minute walk test in outpatients with psychosis

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Abstract

The aim of this study was to investigate the test-retest reliability of the 2-minute walk test (2MWT) and the concurrent validity with the 6-minute walk test (6MWT) in outpatients with psychosis. We also explored whether there was a practice effect, determined minimal detectable changes (MDC) and assessed which factors are associated with the 2MWT performance. Fifty outpatients [22 women; 33.5 (14.3) years] performed the 2MWT twice and the 6MWT once and completed the Simple Physical Activity Questionnaire (SIMPAQ) and Brief Symptoms Inventory -18. The median (interquartile) 2MWT score on the first and second test were 128.0 (44.0) meters and 128.0 (31.5) meters, without significant difference between the two trials. The intraclass coefficient was 0.94 (95% confidence interval=0.91-0.97). The significant Spearman Rho correlation between the second 2MWT and the 6MWT was 0.69. The MDC was 22 meters for men and 21 meters for women. There was no evidence for a practice effect. Variability in SIMPAQ sedentary, exercise, incidental physical activity and leg pain following the test explained 54.6% of the variance in 2MWT score. The current study demonstrates that the 2MWT is a reliable, valid and clinically feasible tool for assessing and evaluating the functional exercise capacity in outpatients with psychosis.

Keywords: fitness; physical activity; walk test; psychosis; schizophrenia

1. Introduction

Despite the recognition that psychosis imposes worldwide a tremendous mental and physical health burden (Morgan et al., 2014; Stubbs et al., 2016a), lifestyle interventions designed to address medical co-morbidities are still scarcely used in treatment programs (Vancampfort et al., 2019). To the best of our knowledge, currently only a few screening, monitoring and treatment guidelines refer to the role of physical activity, and its structured form exercise, in people with psychosis and no single guideline has an adequate focus on the importance of physical fitness testing within this population (Brendon et al., 2018; Mitchell et al., 2012; Vancampfort et al., 2012a; Vancampfort et al., 2015a). This is surprising as physical fitness is not only related to physical health but is also strongly associated with mental health outcomes. For example, a higher physical fitness is associated with a lower risk for psychotic episodes (Kunutsor et al., 2018). Therefore, fitness testing is not only useful for guiding exercise prescriptions, it also can be an important screening tool for assessing those at a higher risk for relapse (American College of Sports Medicine, 2013; Vancampfort et al., 2015a).

Previous research demonstrated that the 6 minute walk test (6MWT) is a reliable and valid test that can be used in clinical practice (Bernard et al., 2014). However, the available evidence has not been translated yet in changes in clinical practice and the 6MWT is not used in standard care packages in most parts of the world (Bernard et al., 2014). One of the reasons why the 6MWT is underutilized in clinical settings is the limited time of the existing work staff (Mugisha et al., 2019). Therefore, even briefer fitness tests than the 6MWT might be more useful and used more in busy clinical settings. The 2-minute walk test (2MWT) is such a short test. The 2MWT is a safe, easy to administer and inexpensive physical fitness test. It evaluates in two minutes the global and integrated responses of the cardiovascular, peripheral circulation and neuromuscular systems involved during exercise (Bohannon et al., 2014). It assesses the sub-maximal level of physical fitness (ATS, 2002). Because most activities of daily living are performed at sub-maximal levels of exertion, the 2MWT may better reflect the functional capacity of a person or the capacity to perform daily physical activities (i.e. functional exercise capacity), which is a

part of a person's overall physical fitness (Bohannon et al., 2014). Despite the potential clinical value, the reproducibility and validity of the 2MWT has not been assessed among patients with psychosis. Previous research in other clinical populations such as people with multiple sclerosis (Scalzitti et al., 2018) and people with dementia (Chan and Pin, 2019), demonstrated good construct and discriminant validity of the 2MWT, providing an efficient and practical alternative to the 6MWT.

The primary aim of the present study therefore was to investigate the test-retest reliability of the 2MWT and the concurrent validity with the 6MWT in outpatients with psychosis. Secondary aims were: (a) to explore whether there was a practice effect with repeated testing, (b) to determine limits for the smallest difference that indicated a real change, and (c) to assess clinical and demographic characteristics that might interfere with performing the 2MWT.

2. Methods

2.1. Participants

Over a 5-month period, all outpatients with a DSM 5 diagnosis of psychosis (American Psychiatric Association) of Butabika National Referral Hospital in Uganda (Kampala) were invited to participate. Participants were excluded if they had significant cardiovascular, neuromuscular and endocrine disorders, which, according to the American College of Sports Medicine (ACSM, 2013), might prevent safe participation in the study. Participants were requested to refrain from eating a heavy meal, drinking tea/coffee or smoking during a two-hour period prior to the tests in order to avoid interaction with the test performance. All outpatients performed the first 2MWT and afterwards completed the Simple Physical Activity Questionnaire (SIMPAQ) (Rosenbaum and Ward, 2016), and the Brief Symptoms Inventory -18 (BSI-18) (Derogatis, 2001). Following completion of the questionnaires, they performed a 6 minute walk test (ATS, 2002) after a two hours rest period to that fatigue or any physical pain would interfere. The second 2MWT was repeated a day later on the same hour of the day and if not possible for practical reasons within two days to avoid that fatigue or any physical pain would interfere with the second test performance. The study procedure was approved by the ethical committee of Mengo Hospital, which covers also the Butabika National Referral Hospital. The research was conducted in accordance with the principles of the Declaration of Helsinki. All participants gave their informed written consent.

2.2. Sample size analysis

An a-priori sample size calculation was conducted following recommendations for reliability analyses (Walter et al., 1998). With a more than acceptable intraclass correlation coefficient (ICC) of 0.80, and alpha of 0.05 and power of 0.8 ($\beta=0.2$) it was established that 46 participants were required in the final analysis (Walter et al., 1998). It was anticipated that approximately 10 to 20% of patients approached would be excluded, and 10% would refuse for motivational reasons. Therefore, a pre-specified sample

size of 55 to 60 participants was utilized to account for these factors in order to ensure the final analysis was adequately powered.

Test-retest 2MWT and concurrent validity with the 6MWT

A test-retest design was used to test the reproducibility and validity of the 2MWT. The test was performed according to the American Thoracic Society guidelines in an indoor corridor with lack of external stimuli (ATS, 2002). Two cones 25 m apart indicated the length of the walkway in a quite administration building of the hospital. Participants were instructed to walk back and forth around the cones during 2 or 6 minutes, without running or jogging. Resting was allowed if necessary, but walking was to be resumed as soon as the participants were able to do so. The protocol (see Appendix) stated that the testing was to be interrupted if threatening symptoms appeared, including (a) chest pain, (b) intolerable dyspnea, (c) leg cramps, (d) staggering, (e) diaphoresis, and (f) pale or ashen appearance (ATS, 2002; Bohannon et al., 2015). Standardised encouragements were provided in Luganda or English (if not Luganda – speaking) at recommended intervals. The total distance walked in 2 or 6 minutes was recorded to the nearest decimetre. All supervisions and measurements of the walk test were performed by the same trained occupational therapist with 3 years of expertise in working with people with psychosis. Prior to the first 2MWT, participants were asked for conditions that might interfere with their functional exercise capacity. They were asked whether they had known hip problems or pain, foot or ankle static problems or pain in the 30 days before the test. Moreover, they were asked to state if they suffered at least sometimes from knee or lower back pain in the past 3 months. Directly after the first test, patients were also asked to report any physical complaints or discomfort.

SIMPAQ (Rosenbaum and Ward, 2016)

The 5-item Luganda (or English) version of the SIMPAQ requires people being interviewed to account for time spent in bed overnight (box 1), time sedentary, including napping (box 2), time spent walking (box 3), time spent exercising (box 4) and time engaged in incidental activity (e.g. household chores) (box 5), averaged over the past seven-day period. The sum of the hours recorded in the five SIMPAQ boxes should add to approximately 24-hours, providing interviewers with an opportunity to clarify with

participants if significant under or over-reporting has occurred (e.g. total of <18 hours or >30 hours accounted for). We used the time spent sedentary, in incidental physical activity and in moderate to vigorous physical activity (MVPA). For an estimated of total self-reported MVPA time, time spent walking (box 3) and exercising (box 4) were combined to provide total MVPA (hours per week).

BSI-18 (Derogatis, 2001)

Symptoms were assessed with the Luganda (or English) version of the BSI-18 (Derogatis, 2001). The BSI-18 (Derogatis, 2001) is a self-reported screening inventory designed to assess participants' level of psychological distress on three dimensions: somatization, depression, and anxiety. The 18 items are divided equally across the three dimensions and were presented with the standard instructions asking participants to rate how much they have been "distressed or bothered" in the past 7 days, including today, by the given symptom, using a 5-point Likert scale ranging from 0 (not at all) to 4 (extremely). Each item contributes to only one subscale, which is scored by summing the scores on each of the six subscale items. The three raw subscale scores range from 0 to 24. The questionnaire was interviewer-administered.

Smoking behavior

Participants were asked whether they smoked or not, and if so, how many cigarettes they smoke per day on average.

Anthropometric measurements

Body weight was measured in light clothing to the nearest 0.1kg using a SECA beam balance scale, and height to the nearest 0.1cm using a wall-mounted stadiometer.

Medication use

Psychotropic medication use was retrieved from the medical files for all included participants.

Statistical analysis

Continuous data were assessed for normality using the Shapiro-Wilk test. The only normally distributed variable was BMI which was presented as mean \pm standard deviation (SD). The other, non-normally

distributed variables were expressed as medians (interquartile range). The ICC between the two 2MWTs using a one-way random single measures intraclass correlation analysis and its associated 95% CI were calculated to objectively assess reliability between two 2MWTs. The concurrent validity of the second 2MWT with the 6MWT was assessed via a Spearman Rho correlation. To assess whether there was a practice effect with repeated testing, the three following methods were used; (a) an ICC of less than 0.75 for the two 2MWTs, (b) a statistically significant improvement in the 2MWT scores between two trials evaluated with the Wilcoxon matched pairs hypothesis test comparing test and retest measurements, and (c) a Spearman Rho correlation of less than 0.75 between the two 2MWTs. Because previous studies did not operationally define practice effects and no single method of evaluation has been identified as superior to the others, the present study considers in parallel with a previous studies (Vancampfort et al., 2015b; Vancampfort et al., 2015c) that a practice effect was to be present only if all three criteria were fulfilled. The minimal detectable change (MDC) for both men and women is calculated by multiplying the standard error of measurement (SEM) by 1.96 to correspond to the 95% CI and the square root of 2 to adjust for sampling from 2 different measurements. The SEM is estimated as the pooled standard deviation (SD) of pre-test and post-test assessments multiplied by the square root of (1-ICC) (de Vet et al., 2006). The SEM quantifies the within-subject variability and takes the amount of measurement error into consideration. MDC_{95} means one can be 95% confident that a change score equal or exceeding this threshold is true and reliable and not just a measurement error (Portney and Watkins, 2000). Correlates with the second 2MWT were assessed with a Spearman Rho or Pearson correlation coefficient when differences in 2MWT scores between two groups (e.g. men versus women) were assessed with a student-t or Mann Whitney U test when appropriate. A backward stepwise multivariable regression analysis was performed to evaluate independent variables explaining the variance in the 2MWT performance. To prevent overfitting of the models, only variables significant ($P < 0.05$) in univariate analyses were entered into the final model. To test for multicollinearity, a variance inflation factor was computed for each independent variable in the model. Values above 3 were used to indicate a multicollinearity problem in the model. The difference in age between men and women was explored with a Mann Whitney U test. A priori, a two sided level of significance was set at $P < 0.05$. Statistical analysis was performed using the statistical package SPSS version 25.0 (SPSS Inc., Chicago, IL).

Results

Participants

A total of 55 outpatients with psychosis were initially screened. Three people were excluded as a consequence of a cardiovascular or neuromuscular disorder that may have prevented safe participation. Of the 52 eligible people with psychosis, two declined to participate (i.e., were not interested). In total, 50 [22♀, median (interquartile range) age= 33.5 (14.3)] participants were included in the final analysis. There was no significant difference in age between men and women ($P= 0.055$). All participants were Ugandan natives and only one patient (2%) of the participants smoked, and this five cigarettes per day. In total, 43 patients had a diagnosis of brief psychotic disorder, six schizophrenia, and one bipolar disorder with psychotic features. An overview of the medication use of the entire sample is presented in Table 1. The majority (72%) was on mono-pharmacotherapy. No patient was drugs-naïve. Patients were more often treated with first generation antipsychotics (60% of the participants) with chlorpromazine the most used one (18%). Twenty percent ($n=10$) was treated with a second-generation antipsychotic with olanzapine the most commonly used one (12%). Other patients were treated with either antidepressants or mood stabilizers, i.e. 10% received an antidepressant, and 16% a mood stabilizer. No participants were treated with somatic medication. Before the first 2MWT, 8% ($n=4$) of patients with psychosis reported suffering from hip pain and 18% ($n=9$) from feet or ankle static problems or pain. Ten patients (20%) complained of at least sometimes having pain in their knees during the previous three months and 42% ($n=21$) reported experiencing lower back pain at least sometimes during the previous three months. Following the 2MWT, patients with psychosis experienced most often **leg** pain (20%, $n=10$), followed by dyspnea (12%, $n=6$). Other demographical and clinical variables are presented in Table 2.

Insert Table 1 about here

Reliability and concurrent validity with the 6MWT of the 2MWT

The median (interquartile) 2MWT score on the first and second test were 128.0 (44.0) meters and 128.0 (31.5) meters, respectively, without significant difference between the two trials ($P=0.91$). In men this was 137.0 (46.5) meters and 137.0 (47.2) meters ($P=0.91$) and in women 123.5 (34) meters and 123 (30) meters ($P=0.91$), respectively. Analyses of reproducibility of the 2MWT showed that the ICC was 0.94 with a 95% confidence interval of 0.91 to 0.97. In men, this was 0.94 (95% CI = 0.88 – 0.97) and in women 0.94 (95% CI = 0.86 – 0.97). The median (interquartile) distance achieved on the 6MWT was 389.5 (83.5) meters, in men this was 405.0 (131.7) meters, and in women 362.0 (79.5) meters. There was a significant correlation with the 6MWT. The Spearman Rho correlation between the second 2MWT and the 6MWT was 0.69 ($P<0.001$), in men this was 0.70 ($P<0.001$), and in women 0.64 ($P=0.001$).

Minimal detectable changes of the 2MWT

The MDC₉₅ in the present study was 22 meters for men and 21 meters for women.

Determination of a practice effect

There was no practice effect since the ICC was more than 0.75 for the two 2MWTs, the 2MWT scores between two trials was not significant ($P=0.91$) and the Spearman Rho between the two 2MWTs was less than 0.75 and this for both men and women.

Factors affecting the second 2MWT

Spearman Rho or Pearson correlations with the MWT are presented in Table 2. The 2MWT was significantly ($P<0.05$) associated with the SIMPAQ sedentary, walking, exercise and incidental physical activity scores. Patients who experienced any locomotor problem before the test walked significantly less, i.e. 121.5 (39.0) versus 136.0 (43.2) meters ($P=0.002$). Also those who experienced leg pain following the test walked significantly less distance on the 2MWT [112.0 (35.0) versus 136.0 (29.5) meters, $P<0.001$. All significant ($P<0.05$) continuous (SIMPAQ sedentary, walking, exercise and incidental physical activity) and dichotomous (i.e. gender, presence of locomotor pain before the test and leg pain following the test) correlates of the 2MWT in univariate analyses were included in the backward stepwise regression analysis. SIMPAQ walking had a variance inflation factor of more than 3, and was removed. SIMPAQ sedentary, SIMPAQ exercise, SIMPAQ incidental physical activity and leg

pain following the test remained significantly associated with the 2MWT distance (see Table 3). The final model explained 54.6% of the variance in the distance walked on the 2MWT.

Insert Tables 2 and 3 about here

Discussion

To the best of our knowledge, the current study is the first to explore the test-retest reliability and concurrent validity of the 2MWT in people with psychosis. Our data show that the 2MWT has an excellent test-retest reliability with an ICC of 0.94 (95% CI = 0.91 - 0.97) and an excellent concurrent validity with the 6MWT demonstrated by a Spearman Rho correlation of 0.69 ($P < 0.001$).

Our data also demonstrate that none of the different methods used to detect a practice effect showed indications of such an effect. An important implication is that a practice walk is not required and that one single test provides sufficiently accurate information. Adequacy of one single test has relevant research and clinical consequences since repeated tests are often difficult to implement in clinical trials and are less feasible and not cost-effective within busy clinic settings. Also of clinical relevance, since only 9.1% was either not eligible or not motivated, the 2MWT can be used to assess and evaluate the functional exercise capacity of the vast majority of patients. The 2MWT does not require any technical equipment nor extensive training, and therefore can be used on a large scale in low income and/or busy settings.

When using the 2MWT, interpreting change scores and identifying clinically significant changes should be an explicit focus. Clinicians are encouraged to understand how changes in scores translate into clinical relevance. The MDC_{95} provides meaningful criteria for assessing changes. Our data show that an improvement of 22 meters for men and 21 meters for women on the 2MWT implies that changes greater than these distances are necessary to be 95% certain that the changes are not due to measurement error or patient variability.

An important observation of the current study was that leg pain following the test was associated with an impaired functional exercise capacity. The finding that musculoskeletal pain is a negatively associated with the functional exercise capacity of persons with psychosis is important. Previous

research, largely among high income countries, has demonstrated that self-report clinical pain affects a third of people with schizophrenia (Stubbs et al., 2014). However, experimental pain induction studies have found that pain threshold and tolerance is increased in people with schizophrenia compared to matched controls (Stubbs et al., 2015). From our data, it was not possible to determine to which extent the comorbid pain has an exact impact on activities of daily life. The present study is the first to show that in particular leg pain following activities is associated with a lower functional exercise capacity. Therefore, assessment of clinical pain should also become a standard practice when assessing performance of daily life activities. Future research should explore how this can be done at low cost and within a minimum amount of time.

It was also observed that the time captured from the SIMPAQ sedentary, SIMPAQ exercise, SIMPAQ incidental physical activity measures are associated with the 2MWT performance. Previous research has shown that people with psychosis are more sedentary and less physically active than matched controls from the general population (Stubbs et al., 2016b; Stubbs et al., 2016c) and that physical inactivity (i.e. not meeting physical activity recommendations) is associated with mental and physical co-morbidity (Stubbs et al., 2016; Vancampfort et al., 2016), also in people with psychosis in Uganda (Vancampfort et al., 2017). The observed associations provide preliminary evidence for the importance of considering both, sedentary and physical activity behavior of people with psychosis when trying to improve their functional exercise capacity. Not only structured physical activity, i.e. exercise should be considered, but also incidental physical activity during daily life. However, our findings should be confirmed in longitudinal and intervention studies.

The reason why BSI-18 depression, anxiety and somatization scores were not associated with the 2MWT scores may be owing to the fact that only outpatients who are at least partially recovered were included. This is reflected in the relatively low BSI-18 scores. Future research should however explore to what extent psychotic or other schizophrenia symptoms interfere with the 2MWT performance. Previous research in people with schizophrenia demonstrated that the distance achieved on the 6MWT was significantly related to the global assessment of functioning score, to negative symptoms, depressive symptoms, cognitive symptoms, the body mass index, smoking behavior, and dose of antipsychotic medication (Vancampfort et al., 2012b).

Data from the present study should be interpreted in the light of some limitations. First, the internal validity of the current study could have been improved by adding an age- and gender matched

control group. Future research comparing 2MWT scores in people with psychosis with an age- and sex-matched healthy control group could provide a valuable point of reference. Second, we only included outpatients and no inpatients and this from the only national referral center of Uganda. This questions the generalizability of the findings. In the regional referral centers, mental health facilities and care are much less developed. However, the sample size was adequately powered and calculated a-priori. Third, our data are cross-sectional and cannot establish cause and effect. Future prospective studies should better disentangle the impact of for example musculoskeletal pain on the functional exercise capacity. Such studies should also explore the extent to which people with psychosis are more or less responsive to behavioural, pharmacological, and non-pharmacological treatments for chronic pain. Further, strategies to encourage people with psychosis to become more physically active and that do not exacerbate pain are likely to be key in improving the functional outcome of these patients. Finally, the majority of the patients were treated with first-generation antipsychotics which are known to have extrapyramidal adverse effects (Zhang et al., 2013). It remains to be explored to what extent these side-effects had an effect on the 2MWT performance.

In conclusion, the 2MWT is a reliable, valid and clinically feasible tool for evaluating the functional exercise capacity in outpatients with psychosis. Clinicians should take into account musculoskeletal symptoms and previous physical activity behaviour when performing physical fitness tests in this population. In daily clinical practice, no practice tests are needed. Improvements of 22 meters for men and 21 meters for women will indicate clinically important changes behind measurement error or patient variability.

Conflicts of interest

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Table 1. Psychotropic medication use in Ugandan outpatients with psychosis (n=50)

Type	Number (%)
Mono-pharmacotherapy	36 (72%)
Poly-pharmacotherapy	14 (28%)
First generation antipsychotics	
Chlorpromazine	9 (18%)
Haloperidol	6 (12%)
Fluphenazine	6 (12%)
Zuclopentixol	3 (6%)
Trifluoperazine	2 (4%)
Second generation antipsychotics	
Olanzapine	6 (12%)
Risperidone	3 (6%)
Quetiapine	1 (2%)
Antidepressants	
Fluoxetine	5 (10%)
Mood stabilizers	
Carbamazepine	6 (12%)
Sodium valproate	1 (2%)
Lamotrigine	1 (2%)
Other	
Artane	31 (62%)

Table 2. Spearman Rho or Pearson correlations with the second 2MWT performance in outpatients with psychosis (n=50)

Variables	mean±SD or median (IQR)	r with 2MWT	P
Age (years)	33.5 (14.3)	-0.17	0.25
Body mass index	21.9±1.8	-0.01	0.95
SIMPAQ sedentary time (hr/day)	11.0 (5.0)	-0.57	<0.001*
SIMPAQ walking (min/day)	0.0 (5.5)	0.31	0.024*
SIMPAQ exercise (min/day)	0.0 (0.0)	0.47	0.001*
SIMPAQ incidental PA (min/day)	30.0 (21.2)	0.40	0.004*
BSI depression	11.5 (7.5)	-0.25	0.08
BSI anxiety	10.0 (5.0)	-0.11	0.44
BSI somatization	10.0 (5.0)	-0.22	0.12

*Significant when $P < 0.05$; SD = standard deviation IQR = interquartile range, 2MWT = 2 minute walk test, PA = physical activity, SIMPAQ = Simple Physical Activity Questionnaire, BSI = Brief Symptoms Inventory.

Table 3. Backward linear regression analysis with the distance walked on the 2 minute walk test as the dependent variable in people with psychosis (n=50)

Variables ^o	B	SE	β	t	P*
(Constant)	181.1	16.7	/	10.9	<0.001*
SIMPAQ sedentary	-5.0	1.3	-0.4	-3.7	0.001*
SIMPAQ exercise	0.7	0.3	0.2	2.2	0.035*
SIMPAQ incidental	0.4	0.1	0.3	2.9	0.005*
Leg pain post-test	-15.2	8.4	-0.2	-1.9	0.007*

^oOnly significant correlates were included in the model (i.e. SIMPAQ sedentary, SIMPAQ walking, SIMPAQ exercise, SIMPAQ incidental physical activity, gender, presence of locomotor pain before the test and leg pain following the test), *significant when $p < 0.05$, B=unstandardized coefficient, SE= standard error, β =standardized coefficient, SIMPAQ = Simple Physical Activity Questionnaire.